

**REMARKS**

Claims 1 and 20 have been amended. Claims 36-46 and 53-55 have been withdrawn. Thus, claims 1 - 35 and 47 - 52 remain pending in the present application. No new matter has been added. In view of the above amendments and the following remarks, it is respectfully submitted that all of the presently pending claims are allowable.

Claims 1 - 4, 6, 9, 10, 12-19, 21, 23, 27, 28, 30 - 35 and 47 - 55 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Published Appln. No. 2005/0038371 to Reich et al. ("Reich") in view of U.S. Published Appln. No. 2004/0116789 to Cancro et al. ("Cancro").

Claim 1 recites a method of treating a central nervous system (CNS) disorder, comprising the steps of "inserting into a patient's body first and second conduits so that distal ends of the first and second conduits open to a portion of the patient's CNS with direct access to cerebrospinal fluid (CSF) and so that a proximal end of the first conduit opens into a first reservoir of material to be introduced into the CSF and a proximal end of the second conduit opens to drain CSF withdrawn from the CNS and permanently prevent the withdrawn CSF from reentering the CNS" in combination with "*detecting and analyzing brain activity of a patient*" and "determining a chemical imbalance present in the CSF based on the detected and analyzed brain activity" and "treating the patient based on the determined chemical imbalance by one of supplying an agent to the CSF via the first conduit and withdrawing a quantity of CSF via the second conduit."

Initially, it is respectfully submitted that Reich fails to teach or suggest a method comprising "detecting and analyzing brain activity of a patient" and "determining a chemical imbalance present in the CSF based on the detected and analyzed brain activity," as recited in claim 1. Rather, Reich makes no disclosure of the a detection of brain activity at all and the Examiner has referenced Cancro to overcome this deficiency. However, it is respectfully submitted that Cancro, too, fails to teach the aforementioned limitations. Specifically, Cancro includes no teaching or suggestion to determine a chemical imbalance in CSF based on detected brain activity. Cancro is limited to the monitoring "an area of the brain which gives rise to [a] disorder, or which is affected by [a] drug being tested" by using a source localization technique such as Magnetoencephology. (*See* Cancro, ¶ [0011] and [0014] - [0019]). Cancro neither teaches nor suggest a correlation between detected brain activity and any chemical imbalance in

the CSF. Cancro explicitly indicates that the brain activity is monitored only to determine areas in which abnormal activity is present. The disorder is then diagnosed and treated by administering a drug. (*Id.*). The mere fact that Cancro teaches detection of brain activity is not enough to overcome the fact that neither Cancro nor Reich teaches or suggests a method comprising “determining a chemical imbalance present in the CSF *based on the detected and analyzed brain activity*,” as recited in claim 1.

It is therefore respectfully submitted that neither Reich nor Cancro, taken alone or in combination, teach or suggest a method comprising “detecting and analyzing brain activity of a patient,” “determining a chemical imbalance present in the CSF based on the detected and analyzed brain activity,” and “treating the patient based on the determined chemical imbalance by one of supplying an agent to the CSF and withdrawing a quantity of CSF via the second conduit,” as recited in claim 1. It is submitted that claim 1 and its dependent claims 2 - 4, 6, 9, 10, 12 - 19 and 47 - 49 are allowable over Reich and Cancro for at least this reason.

Furthermore, it is respectfully submitted that the proposed combination of Reich and Cancro would change the principle of operation of Reich and is therefore not allowable. Specifically, Reich teaches an infusion and withdrawal of fluids, a flow rate thereof being affected by sensors that determine if the patient is in an upright or supine position to account for changes in gravity. (*See* Reich, ¶ [0024], [0036] - [0037]; Fig. 1). Modifying the Reich device so that the infusion and withdrawal rates are dependent on a “determined chemical imbalance,” as recited in claim 1, would change the principle of operation of the Reich device by obviating the need for the supine and upright withdrawal modes and rather making the delivery and withdrawal of fluids from the patient dependent on brain activity. Reich makes no disclosure of the relevance of “brain activity,” as recited in claim 1, to the device taught therein and explicitly indicates the importance of providing an equilibrium between under-drainage in a lying position and over-drainage in an upright position irrespective of brain activity. (*See* Reich, ¶ [0012] - [0013]). Accordingly, modification of the Reich device to affect an infusion or withdrawal of CSF based on a determined chemical imbalance, as indicated in claim 1, would interfere with the function of providing such a function based on a patient’s position and thus, change the principle of operation thereof. It is therefore submitted that the proposed modification is not allowable and claim 1 is allowable for at least this additional reason. It is respectfully submitted that claim 1 and its dependent claims 2 - 4, 6, 9, 10, 12 - 19 and 47 - 49 are allowable over Reich and Cancro

for at least this additional reason.

Claim 15 recites a method comprising the steps of “embedding at least a portion of one of a quantitative electroencephalography system and a brainstem auditory evoked response system within the patient’s body to *detect and analyze brain activity* to identify brain activity *corresponding to a predetermined imbalance within the CSF*” and “controlling the first and second pumps automatically based on output from the one of a quantitative electroencephalography system and a brainstem auditory evoked response system to *correct the imbalance*.”

The Examiner has affirmed that Reich does not teach or suggest brain activity detection. (See 5/28/08 Office Action, p. 2). The Examiner has not provided any specific argument with respect to claim 15. However, it is respectfully submitted that Cancro, too, fails to teach or suggest the aforementioned limitations. Specifically, Cancro is directed to a system and method of performing 3-D brain source localization to detect regions of abnormality in the brain so that the abnormality may be treated through the administration of a drug. (See Cancro, ¶ [0014] - [0019]; [0022]). It is respectfully submitted that Cancro fails to teach the step of “embedding at least a portion of one of a quantitative electroencephalography system and a brainstem auditory evoked response system within the patient’s body to *detect and analyze brain activity* to identify brain activity *corresponding to a predetermined imbalance within the CSF*,” as recited in claim 15. As described above, Cancro neither teaches nor suggest a correlation between detected brain activity and an imbalance in the CSF. It is therefore submitted that claim 15 is allowable over Reich and Cancro for at least this reason.

Furthermore, it is respectfully submitted that Reich and Cancro fail to teach or suggest the step of “controlling the first and second pumps automatically based on output from the one of a quantitative electroencephalography system and a brainstem auditory evoked response system to correct the imbalance,” as recited in claim 15. Rather, since neither Reich nor Cancro addresses detection of an imbalance in CSF by one of quantitative electroencephalography and a brainstem auditory evoked response, it follows that “controlling the first and second pumps automatically based on the output from the one of a quantitative electroencephalography system and a brainstem auditory evoked response system to correct the imbalance” as recited in claim 15, is also neither taught nor suggested therein. It is therefore respectfully submitted that claim 15 is

allowable over Reich and Cancro for at least this additional reason.

Claim 20 recites limitations substantially similar to claim 1, including a system for treating disorders of the central nervous system (CNS), comprising first and second conduits having distal ends which, when in an operative position, “open into a portion of a patient’s CNS with direct access to cerebrospinal fluid (CSF) and wherein, when in the operative position, a proximal end of the second conduit opens to drain CSF from the CNS and permanently prevent the drained CSF from reentering the CNS” and a first pump coupled to a reservoir holding a first material and “the first conduit for introducing the first material to the CNS via the first conduit” in combination with “*a brain activity detection unit for detecting and analyzing a chemical imbalance present in the CSF based on the brain activity of the patient.*”

As noted earlier, neither Reich nor Cancro teaches or suggests “a brain activity detection unit for detecting and analyzing a chemical imbalance present in the CSF based on the brain activity of the patient,” as recited in claim 20. Specifically, neither Reich nor Cancro suggests a correlation between brain activity and a chemical imbalance in the CSF. Furthermore, as also noted earlier, since the device of Reich is directed to the maintenance and enhancement of a cerebrospinal fluid turnover rate and the maintenance of an equilibrium between under-drainage in a lying position and over-drainage in an upright position, neither reference provides any motivation for the combination proposed by the Examiner. (See Reich, ¶ [0012] - [0013]). Rather, modification of the Reich device to affect an infusion or withdrawal of fluid based on brain activity detection, as indicated in claim 20, would interfere with the function of maintaining a desired drainage rate as a patient’s position changes (e.g., supine or standing). Thus, it is respectfully submitted that claim 20 and the claims 21, 23, 27, 28, 30 - 35 and 50 - 52 dependent therefrom are also allowable over Reich and Cancro for at least the same reasons noted above and with respect to claim 1.

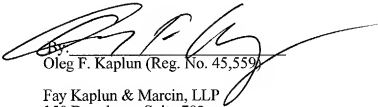
Claims 5, 11, 22 and 29 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Reich in view of Cancro in further view of U.S. Patent No. 6,436,091 to Harper et al. (“Harper”). It is respectfully submitted that Harper does not cure the deficiencies noted above with respect to Reich and Cancro and that claims 5, 11, 22 and 29 are therefore allowable for at least the reasons given above in support of the patentability of claims 1 and 20 from which these claims depend.

Claims 7, 8, 25 and 26 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Reich in view of Cancro in further view of U.S. Published Appln. No. 2003/0130645 to Brengle et al. ("Brengle"). It is respectfully submitted that Brengle does not cure the deficiencies noted above with respect to Reich and Cancro. It is therefore respectfully submitted that claims 7, 8, 25 and 26 are allowable for at least the reasons given above in support of the patentability of claims 1 and 20.

In light of the foregoing, Applicant respectfully submits that all of the presently pending claims are in condition for allowance. All issues raised by the Examiner having been addressed, an early and favorable action on the merits is earnestly solicited.

Respectfully submitted,

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